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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,117	04/02/2004	Ruben G. Carbonell	51821-0111 (51821-299533)	3952
47234	7590	11/28/2006	EXAMINER	
LAW OFFICES OF KHALILIAN SIRA, LLC 9100 PERSIMMON TREE ROAD POTOMAC, MD 20854			BOESEN, AGNIESZKA	
			ART UNIT	PAPER NUMBER
			1648	

DATE MAILED: 11/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/817,117

Applicant(s)

CARBONELL ET AL.

Examiner

Agnieszka Boesen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-52 is/are pending in the application.
- 4a) Of the above claim(s) 7,8 and 34-49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5,6,9-33 and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The Amendment filed September 11, 2006 in response to the Office Action of June 20, 2006 is acknowledged and entered. Claims 1, 2, 5, 6, 10, 12-15, 17, and 31 have been amended. New claims 50-52 have been added. Claims 1, 2, 5, 8, 9-33, and 50-52 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 112

The rejection of claims 14 and 15 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention is maintained.

Applicant argues that the presence of the trademark names in claims 14 and 15 is proper and points out to MPEP section 2173.05(u). Examiner respectfully disagrees because MPEP section 2173.05(u) recites as follows:

If the trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of the 35 U.S.C. 112, second paragraph. Ex parte Simpson, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. In fact, the value of a trademark would be lost to the extent that it became descriptive of a product, rather than used as an identification of a source or origin of a product. Thus, the use of a trademark or trade name in a claim to identify or describe a material or product would not only render a claim indefinite, but would also constitute an improper use of the trademark or trade name.

If a trademark or trade name appears in a claim and is not intended as a limitation in the claim, the question of why it is in the claim should be addressed. Does its presence in the claim cause confusion as to the scope of the claim? If so, the claim should be rejected under 35 U.S.C. 112, second paragraph.

Thus in the present case, because the trademark name is used in a claim as a limitation to identify or describe a particular material or product, the claims do not comply with the requirements of the 35 U.S.C. 112, second paragraph. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 102

Rejection of claims 3 and 4 under 35 USC 102(b) as being anticipated by Foster et al., (2000, Vox Sanguinis Vol. 78, p. 86-95) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) is moot because Applicant canceled claims 3 and 4.

Rejection of claims 1, 2, 5, 6, and 9-33 and new claims 50-52 under 35 USC 102(b) as being anticipated by Foster et al., (2000, Vox Sanguinis Vol. 78, p. 86-95) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) is **maintained.**

New claims 50-52 are drawn to a method of forming and detecting a complex between a prion protein in a sample and prion protein binding material. The functional group comprises hydrophilic group, hydrophobic group, an amphiphilic group, or a combination thereof. The method comprises chromatography, solid support, membrane separation, reactor separation, magnetic separation, immunoseparation, colloidal separation, or a combination thereof.

Foster et al., disclose a method of removal of prion protein from human plasma using Toyopearl amino 650M (see the entire document, particularly the abstract and Table 2 on page 92). The limitations recited in claims 50-52 are an inherent property of the Toyopearl™ AF amino 650 M product as evidenced by Data Sheet and the manual for the product (see Affinity

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Chromatography manual Figure 6 and data sheet page 4). The disclosure by Foster et al., as evidenced by Data Sheet and the manual for the product anticipate the current claims.

Applicant's argument has been fully considered but fails to persuade. Applicant argues that the amendment to the claims obviates the current rejection. Applicant amended the claims to recite, "(...) wherein the prion protein binding material comprises a polymer matrix that binds *specifically and selectively* to the prion protein".

Applicants argue that the cited reference by Foster et al. does not teach the required limitation that the polymer matrix binds specifically and selectively to the prion protein. Examiner respectfully disagrees. The prion binding material disclosed by Foster et al. is exactly the same as the prion binding material used in the currently claimed method, and the prion protein being removed by the referenced method is exactly the same prion protein forming a complex with the prion binding material in the claimed method. Thus the Foster's prion protein is expected to bind and form a complex with Foster's prion binding material. The limitation that the polymer matrix binds specifically and selectively to the prion protein does not distinguish the claimed method over the prior art. Therefore the rejection is maintained.

Rejection of claims 3 and 4 under 35 U.S.C. 102(e) as being anticipated by Hammond et al., (U.S. 6,750,025) is moot because Applicant canceled claims 3 and 4.

Rejection of claims 1, 2, 5, 6, and 9-33 under 35 U.S.C. 102(e) as being anticipated by Hammond et al., (U.S. 6,750,025) is maintained.

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Applicant's argument has been fully considered but fails to persuade. Applicant argues that the detection method of the cited reference is different than the detection method of the current invention, because the Hammond's method detects unknown target binding to an unknown ligand. Examiner respectfully disagrees because Hammond et al., does identify a ligand for prions (see claim 1). The reference also discloses that the identified ligand may be used either for the detection of a known target such as prions, or for the removal of prions from a sample (see, column 2, lines 50-63). As means for carrying out the invention, the reference teaches that the ligand may be attached to the affinity column formed on a resin, including on Toyopearl resins (see, column 5, lines 6-17). The reference further identifies a Toyopearl amino 650 M resin as a Toyopearl resin (column 10, lines 44-46). Based on this disclosure Hammond anticipates the rejected claims.

Applicant also argues that the Hammond's matrix is not covalently attached to the ligand unlike the matrix in the instant application which is a polymeric backbone covalently attached to the ligand. Examiner respectfully points out that the argued limitation of "polymeric backbone covalently attached to the ligand" is not recited in the currently examined claims. Thus Applicant's argument is not found persuasive and therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

Rejection of claims 3 and 4 under 35 U.S.C. 103(a) as being unpatentable over Pruisner (US Patent 6,221,614 B1) in view of Kragten et al., (1998, J Biol Chem 273: 5821-28) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) is moot because Applicant canceled claims 3 and 4.

Rejection of claims 1, 2, 5, 6, and 9-33 under 35 U.S.C. 103(a) as being unpatentable over Pruisner (US Patent 6,221,614 B1) in view of Kragten et al., (1998, J Biol Chem 273: 5821-28) as evidenced by Data Sheet and manual (Affinity Chromatography, Tosoh Bioscience LLC, Cat # 28 A21DS) is maintained.

Applicant's argument has been fully considered but fails to persuade. Applicant argues that the amendment to the claims obviates the current rejection. Applicant amended the claims to recite, "(...) wherein the prion protein binding material comprises a polymer matrix that binds *specifically and selectively* to the prion protein".

Applicant argues that neither Pruisner nor Kragten, alone or in combination render the subject matter of the current invention obvious. Applicant argues that Pruisner does not disclose the specific and selective binding of prion protein to a polymer matrix as required by the invention as claimed. Examiner respectfully disagrees. Pruisner et al. teach a method for detection and removal of prions from blood plasma comprising forming a complex between the prion molecule and a complexing agent (see the entire document, particularly claim 1 and claim 6, column 2 lines 53-67, and column 8 lines 43-56). An example of the complexing agent taught by Pruisner et al. is a polymer matrix coupled to a hydrophobic ligand (see column 12, lines 30-55). Because Pruisner teaches a method for detection and removal of prions from blood plasma comprising forming a complex between the prion molecule and a complexing agent and one of ordinary skill in the art would consider a binding in a complex as selective and specific, thus Pruisner teaches the claimed limitation.

Applicant also argues that Kragten does not cure the deficiency of Pruisner because Kragten does not disclose binding of prion protein to a polymeric matrix. Examiner respectfully

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disagrees. The "binding of prion protein to a polymeric matrix" is not the deficiency that Kragten reference was meant to cure, and "binding of prion protein to a polymeric matrix" is not a deficiency of Prusiner because Prusiner does teach the limitation of "binding of prion protein to a polymeric matrix" (see column 12, lines 30-55). Kragten reference was meant to cure the limitation of a specific polymer matrix such as Toyopearl amino 650. The fact that Kragten's reference does not teach binding of prions to polymer matrix is irrelevant because this limitation is taught by Prusiner. Because Kragten's reference does cure the limitation of a specific polymer matrix such as Toyopearl amino 650, the rejection is maintained.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 2, 5, 6 and 8-33 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-20 of copending Application No. 10/962, 670.

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Applicants requested that the rejection under obviousness double patenting is being held in abeyance until Applicants receive an indication of allowable subject matter in this application.

Claims 1-6 and 8-33 of the instant application are drawn to a method of forming and detecting a complex between a prion protein and prion protein binding material. Claims 1-20 of the reference application are drawn to a method of detecting and separating prion protein from a sample comprising contacting the sample with a polymeric prion protein binding material. The prion binding material both the instant and the reference application is a Toyopearl™ amino 650, a polymer matrix bound to an amine group.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are generic to the present claims. The limitations of the present claims are inherent to the copending claims (i.e. forming and detecting a complex between a prion protein and a prion protein binding material. The present claims are therefore obvious variations of the claims of the copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Agnieszka Boesen whose telephone number is 571-272-8035. The examiner can normally be reached on 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AB
Agnieszka Boesen, Ph.D.
Examiner

11/27/06

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PRIMARY EXAMINER